

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

-----X)	
EMD MILLIPORE CORPORATION,)	Civil Action No. 11-cv-10221 DPW
MILLIPORE AB, and)	
MILLIPORE SAS,)	MILLIPORE’S OPPOSITION TO
Plaintiffs,)	DEFENDANT’S MOTION FOR
)	<u>SUMMARY JUDGMENT</u>
v.)	
)	
ALLPURE TECHNOLOGIES, INC.,)	
Defendant.)	
)	
-----X		

I. Introduction

This is an action to enforce Millipore’s¹ patent, U.S. Patent No. 6,032,543 (“the ’543 Patent”) against infringement by the defendant AllPure Technologies, Inc. (“the defendant” and “AllPure”). The defendant’s TAKEONE Samplers infringe at least Claims 1-3, 5, and 6 of the ’543 Patent. The defendant embarked on its infringing activity in order to enter the sampling market in competition with Millipore’s NovaSeptum[®] product.

Without identifying any undisputed facts in support of its motion as required by Local Rule 56.1, the defendant has asserted that its products do not meet three limitations of Claim 1:

- AllPure claims that its TAKEONE Samplers do not have one or more removable transfer members. However, the evidence shows that the TAKEONE Samples have transfer members, and these transfer members can be removed from the device and replaced.
- AllPure claims that the TAKEONE Sampler does not have a seal with first end having a bellows-shaped part. However, the evidence shows that the TAKEONE Sampler does have a seal with a bellows-shaped part.
- AllPure claims that the TAKEONE Sampler does not have a seal with a self-sealing membrane interiorly formed at an end of the bellows-shaped part. However, the evidence shows that the TAKEONE Sampler does have a seal with a self-sealing membrane interiorly formed at an end of the bellows-shaped part.

¹ “Millipore” refers collectively to the plaintiffs EMD Millipore Corporation, Millipore AB, and Millipore SAS.

The defendant's failure to identify undisputed facts is sufficient grounds for denial of its motion. (*See* Local Rule 56.1). Further, as set forth below, there are at least genuine issues of material fact, and the defendant is not entitled to judgment as a matter of law on the infringement issues it presents for decision. In fact, the defendant's devices not only have the three elements disputed by the defendants, but as shown below, have every element of asserted claims 1-3, 5, and 6. Accordingly, if summary judgment is to be entered following claim construction, it should be *sua sponte* in favor of Millipore. *See* Rule 56 Fed. R. Civ. P.; *Berkovitz v. Home Box Office, Inc.*, 89 F.3d 24, 29 (1st Cir. 1996).

This Opposition is supported by Supplemental Affidavits of Lawrence P. Cogswell, III, Ph.D. and Alexander H. Slocum, Ph.D. and by Millipore's Statement of Contested Facts.

II. Background

A. Summary Judgment Standard

Under Fed. R. Civ. P. 56(c), a party seeking summary judgment must show that "there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." In considering such a motion, "the evidence must at all times be viewed in the light most favorable to the nonmovant, and all doubts and reasonable inferences must be resolved in the nonmovant's favor." *Casas Office Machines, Inc. v. Mita Copystar America, Inc.*, 42 F.3d 668, 684 (1st Cir. 1994). The moving party must first meet its burden to establish that it is entitled to summary judgment as a matter of law before the opposing party is obligated to demonstrate that there are genuine disputes of material fact issues. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 160 (1970); *Carmona v. Toledo*, 215 F.3d 124, 132 (1st Cir. 2000) ("The moving party is said to bear both the initial burden of production and the ultimate burden of persuasion on the motion."). On a motion for summary judgment, "a trial court cannot reach a conclusive finding of noninfringement if the record shows some evidence supporting a finding of noninfringement and

some evidence to the contrary.” *AFG Industries, Inc. v. Cardinal IG Co., Inc.*, 375 F.3d 1367, 1371 (Fed. Cir. 2004).

A claim is literally infringed “if each of the limitations of the asserted claim(s) read on, that is, are found in, the accused device,” *Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1583 (Fed. Cir. 1995). A claim is infringed under the doctrine of equivalents if the accused device contains each limitation of the claim or its equivalent. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997). An element of the accused device is equivalent to a claim limitation if “the differences between the two are insubstantial.” For example, an element is equivalent if it “performs substantially the same function in substantially the same way to obtain the same result as the claim limitation.” *AquaTex Indus., Inc. v. Techniche Solutions*, 419 F.3d 1374, 1382 (Fed. Cir. 2005) (citations omitted). “Infringement under the doctrine of equivalents requires an intensely factual inquiry.” *Toro Co. v. White Consol. Industries, Inc.*, 266 F.3d 1367, 1369 (Fed. Cir. 2001) (quotation marks and citations omitted). Summary judgment on the issue of infringement under the doctrine of equivalents is appropriate only “if the record contains no genuine issue of material fact and leaves no room for a reasonable jury to find equivalence.” *Toro*, 266 F.3d at 1370.

B. U.S. Patent No. 6,032,543

The ’543 Patent, entitled “Device for Introduction and/or Withdrawal of a Medium into/from a Container,” generally relates to fluid sampling devices. A copy of the ’543 Patent is Exhibit 1 to the Affidavit of Lawrence P. Cogswell III, Ph.D. (“Cogswell Affidavit”) (D.I. 31-1) and the file history for the patent is Exhibit 2 to the Cogswell Affidavit. The ’543 Patent discloses devices for one of introduction and withdrawal of a medium into a container. These devices employ a needle that pierces a septum and extends into the container, permitting aseptic withdrawal of fluid samples, while eliminating disadvantages of prior devices. NovaSeptum AB

developed technology that is the subject of the '543 Patent. Millipore AB owns the patent, and commercial embodiments of this technology are manufactured and sold by Millipore as a result of company acquisitions.

Asserted Claims 1-3, 5 and 6 of the '543 Patent appear in Exhibit A to this Opposition.

Claim 1 is reproduced below:

1. A device for one of introduction and withdrawal of a medium into a container having an aperture formed therein for receiving said device, said device comprising:

at least one removable, replaceable transfer member for transferring a medium into and out of the container, said transfer member comprising a holder, a seal for sealing said aperture, a hypodermic needle having a tip, said needle supported within said holder in a longitudinal direction thereof, wherein the seal has a first end comprised of a bellows-shaped part sealingly attached to said holder, and a second end comprising a self-sealing membrane portion interiorly formed at an end of said bellows part, said membrane portion for sealing said aperture of said container, wherein said bellows-shaped part surrounds said needle and is deformable in a longitudinal direction, said membrane portion pierceable by the tip of the needle to form a sealable channel;

a fastening device for sealingly securing the transfer member via the seal with the aperture of the container, thereby forming a closed system, said fastening device comprising a flanged part sealingly secured in the aperture and formed with at least one hole therethrough in communication with an interior of said container, a magazine part for removable securement of said at least one transfer member, and a fastening and centering means for removable locking of the magazine part to a flanged part in a position wherein the membrane portion sealingly abuts against the hole of the flanged part so as to accept the hypodermic needle for introduction into and withdrawal from the container through the membrane portion and the hole.

III. The Defendant Infringes At Least Claims 1, 2, 3, 5, and 6 of the '543 Patent

AllPure's motion for summary judgment of noninfringement should be denied because the accused AllPure Products meet every limitation of, and therefore literally infringe, the asserted claims of the '543 Patent.

A. The Defendant Infringes Claim 1 of the '543 Patent

The defendant's TAKEONE Sampler satisfies each of the limitations of Claim 1, as set forth below:

[Claim 1] A device for one of introduction and withdrawal of a medium into a container having an aperture formed therein for receiving said device said device comprising:

The defendant's TAKEONE Sampler 100 (Figure 1) is a device 100 for introduction and withdrawal of a medium into a container 197 having an aperture 196 formed therein for receiving said device 100. (Figure 2)

Figure 1

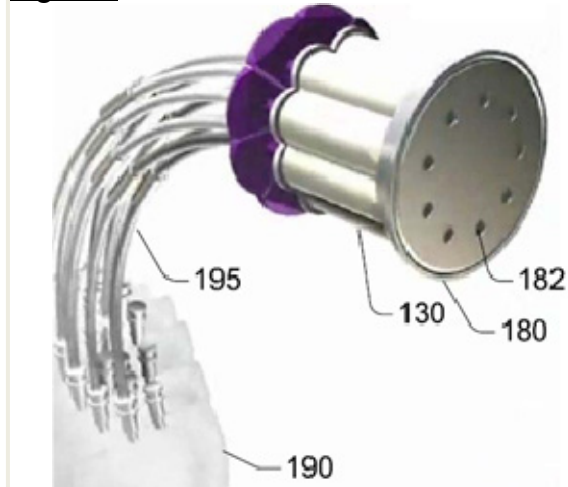
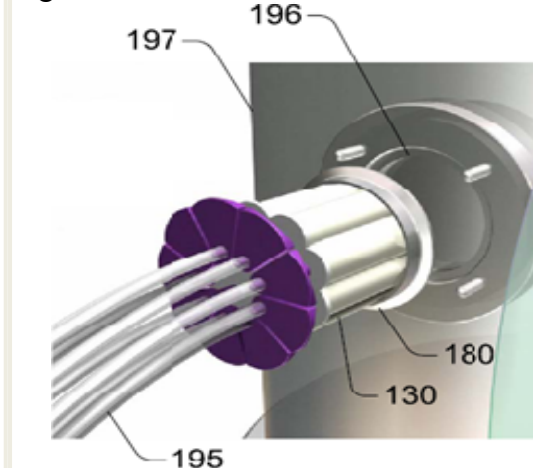


Figure 2

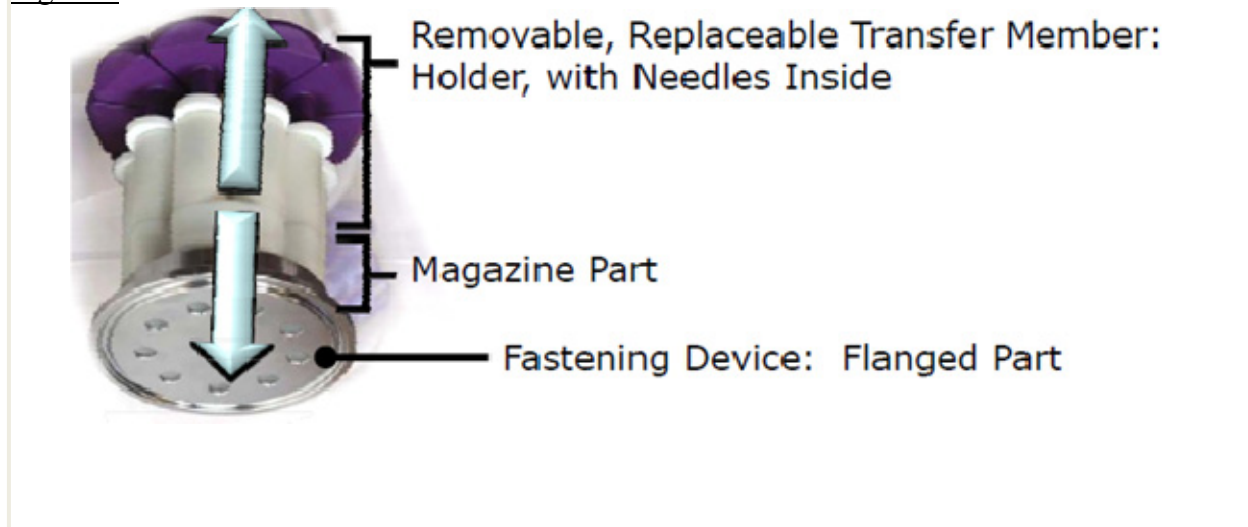


[1] at least one removable, replaceable transfer member for transferring a medium into and out of the container

The defendant's TAKEONE Sampler 100 comprises at least one removable, replaceable transfer member 130 for transferring a medium into and out of the container 197. *See* Figures 1 and 2.

Figure 3 shows where at least one transfer member separates from a magazine part for removal and replacement. Further details on the removal and replacement of the transfer members are provided in the discussion of the next limitation.

Figure 3



[2] said transfer member comprising a holder, a seal for sealing said aperture, a hypodermic needle having a tip, said needle supported within said holder in a longitudinal direction thereof

Figures 4 and 5, below, show top to bottom cross sections of the defendant's TAKEONE Sampler. Figure 4 shows the sampler with the needle retracted, and Figure 5, with the needle extended.

As seen by reference to Figures 4 and 5, transfer member 130 comprises a holder 150, a seal 160 (Figure 4) for sealing the aperture 196 (see Figure 2, showing aperture) formed in the container 197 (Figure 2), and a hypodermic needle 170 having a tip (Figures 4 and 5). The needle 170 is supported within the holder 150 in a longitudinal direction of the holder.

Figure 4

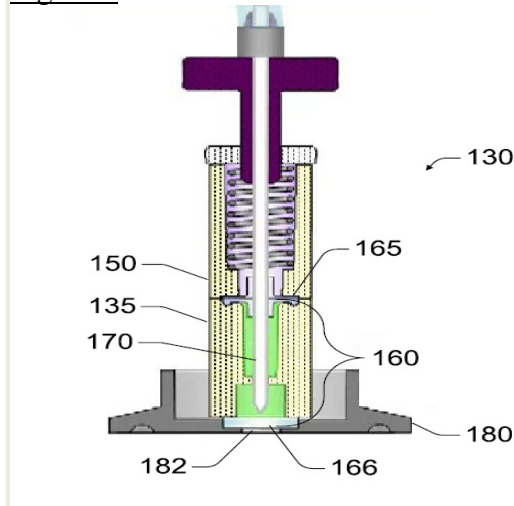
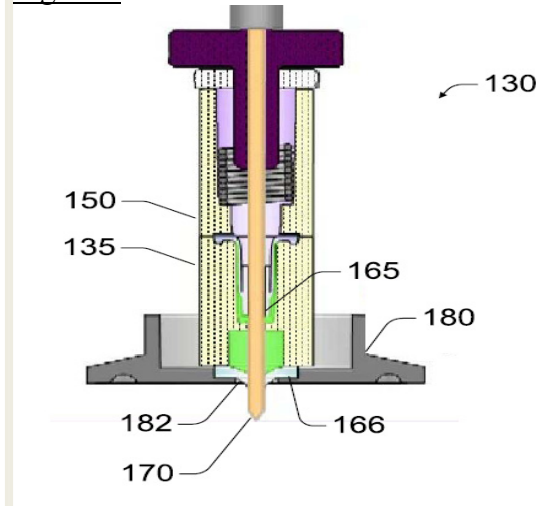


Figure 5



[3] wherein the seal has a first end comprised of a bellows-shaped part sealingly attached to said holder

The seal 160 (Figure 4) has a first end comprised of a bellows-shaped part 165 (Figures 4 and 5) sealingly attached to said holder 150. (See Figure 4).

As explained in the Supplemental Affidavit of Professor Alexander H. Slocum, Ph.D., (“Slocum Afft.”) a Professor of Mechanical Engineering at MIT, a bellows is a part in which longitudinal deformation is enabled by one or more plate-like members. (Slocum Afft. at ¶¶ 13, 21). Figure 6, below, shows the concept of a bellows, where one of the plate-like members is shown in blue, and the bellows has four plate-like members in total. (Slocum Afft. at ¶ 10, and at Ex. 2) The longitudinal deformation of a bellows is enabled by its one or more plate-like members, as shown in Figure 6 (Slocum Afft. at ¶¶ 11-13, and at Ex. 2).

Two plate-like members, taken together, constitute a bellows “convolution,” and a single plate-like member is a half-convolution. (Slocum Afft. at ¶ 14, and at Ex. 2) There are many kinds and sizes of bellows, depending on the number and sizes of plate-like members. A bellows with one plate-like member is known as a half convolution bellows. (Slocum Afft. at ¶ 15-17).

Figure 7, below, shows the first end of the seal of the defendant’s TAKEONE Sampler, showing the bellows-shaped part (165) shaded in blue. Part 165 is a bellows-shaped part,

because, as shown below in Figure 7, its longitudinal deformation is enabled by at least one plate-like member. The bellows has a single plate-like member, and in operation of the device, this plate-like member longitudinally deforms between two states, depicted as A and B in Figure 7. (Slocum Afft. at ¶¶ 23-27, and at Ex. 5)

Figure 6

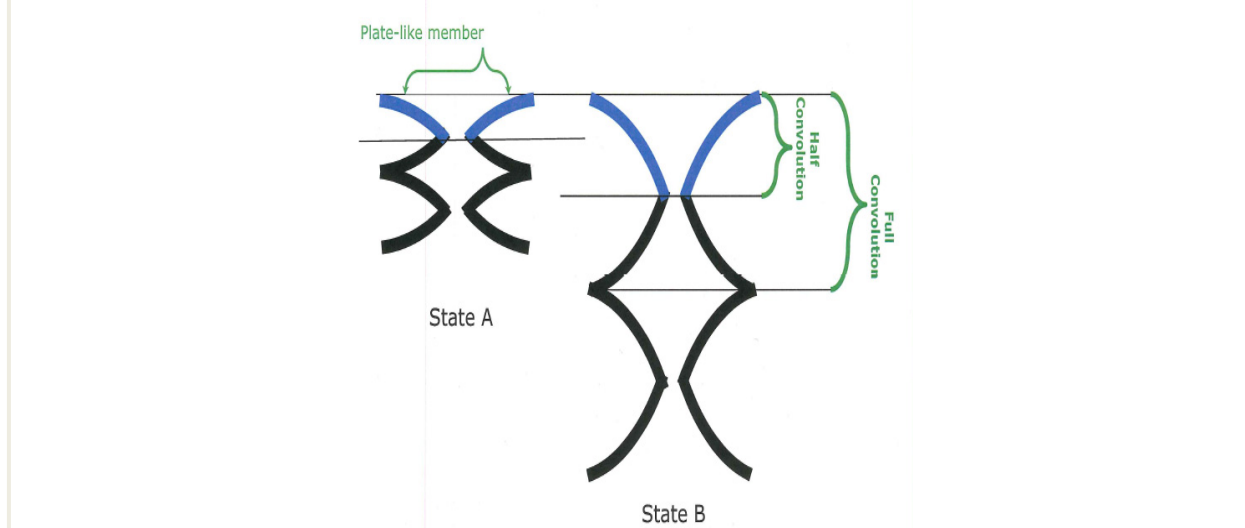
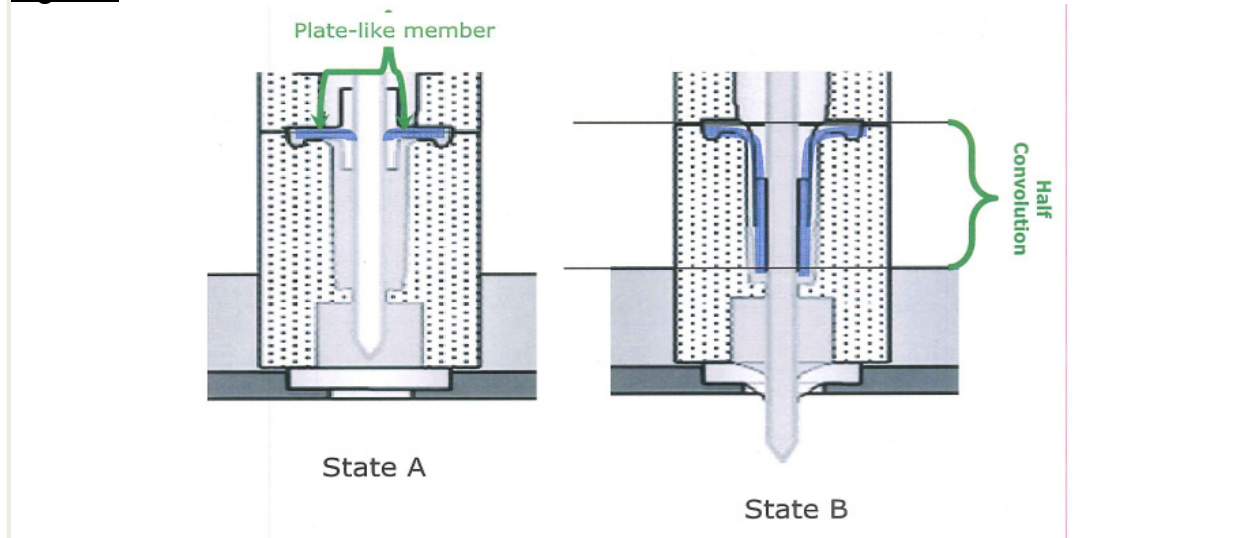


Figure 7



[4] and a second end comprising a self-sealing membrane portion interiorly formed at an end of said bellows part, said membrane portion for sealing said aperture of said container,

The seal 160 (Figure 4) has a second end comprising a self-sealing membrane portion 166 (Figures 4 and 5) that is interiorly formed at an end of said bellows part 165 (Figures 4 and 5)

5). AllPure's Test Report Summary entitled "TAKEONE Aseptic Sampling System: Bacterial Ingress Challenge" ("AllPure's Test Report Summary") states that, "The silicone septa reseal preventing migration of external organisms" Suppl. Cogswell Afft., Ex. 2. The membrane portion 166 seals the aperture of the container.

[5] wherein said bellows-shaped part surrounds said needle and is deformable in a longitudinal direction,

The bellows-shaped part 165 surrounds the needle 170. (Figures 5 and 7) The bellows-shaped part 165 is deformable in a longitudinal direction (Figures 4 and 5, showing deformation of the bellows-shaped part 165; see also Figure 7, showing deformation).

[6] said membrane portion pierceable by the tip of the needle to form a sealable channel;

The membrane portion 166 (Figure 5) is pierced by the tip of the needle 170 to form a sealable channel. The images in Figures 4, 5, 7 and 8 (below) show that the tip of the needle 170 pierces the membrane portion so that there is a channel through which fluid enters in order to reach the hose. Figure 9 shows that the channel is sealable because the device, when it is removed from the aperture after sampling, does not leak.

Figure 8

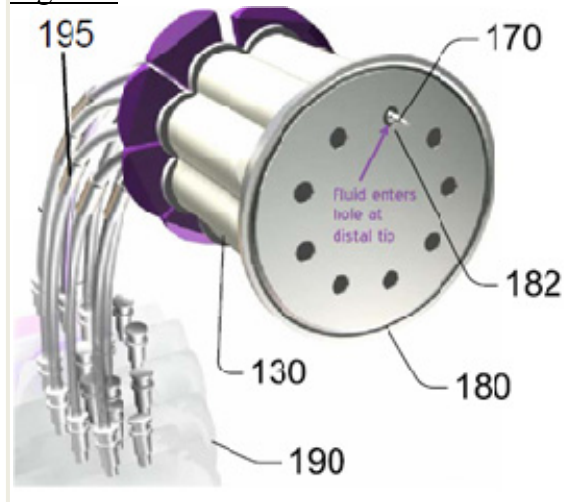
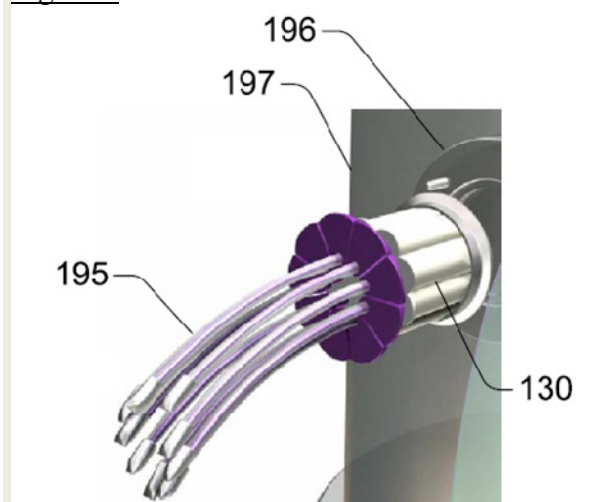


Figure 9



In addition, AllPure's Test Report Summary confirms that:

Each independent sampling mechanism resides inside a closed chamber of the TAKEONE® body. Each chamber is sealed against a platinum-cured septum which is molded into the electropolished 316L stainless steel mount.

* * *

The platinum-cured silicone septa maintains an aseptic barrier before, during and after actuation of the TAKEONE® aseptic sampling system.”) (emphasis added).

[7] a fastening device for sealingly securing the transfer member via the seal with the aperture of the container, thereby forming a closed system,

A fastening device sealingly secures the transfer member 130 via the seal 160 (Figures 4 and 5) with the aperture of the container, thereby forming a closed system. *See* Figure 10. As stated in AllPure’s Test Report Summary, “Each independent sampling mechanism resides inside a closed chamber of the TAKEONE® body. Each chamber is sealed against a platinum-cured septum which is molded into the electropolished 316L stainless steel mount.”

[8] said fastening device comprising a flanged part sealingly secured in the aperture and formed with at least one hole therethrough in communication with an interior of said container,

The fastening device comprises a flanged part 180 sealingly secured in the aperture and formed with at least one hole 182 therethrough in communication with an interior of said container. *See* Figures 10 and 11, below. Figure 11 shows the flanged part 180 in further detail.

Figure 10

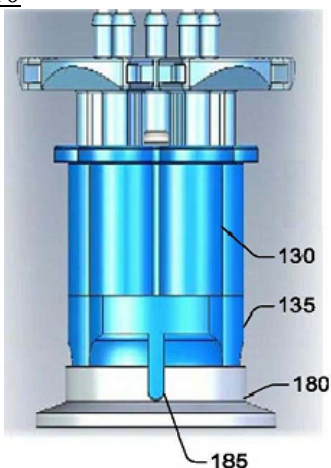
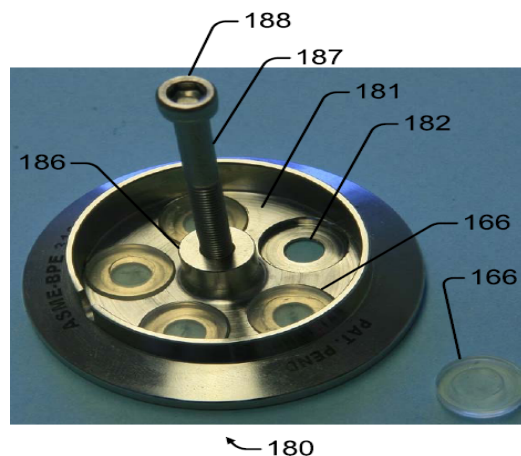


Figure 11



[9] a magazine part for removable securement of said at least one transfer member,

The fastening device comprises a magazine part 135 for removable securement of at least one transfer member 130. *See* Figure 11. The magazine part 135 secures at least one transfer member 130. The transfer member 130 is removable from the magazine part by separating the holder from the magazine part as shown in Figure 3, along with the needle and bellows-shaped part of the seal. When the magazine part is removed from the flanged part 180 (Figure 11), the membrane portions of the seals 166 are no longer secured by the magazine part and may be removed. *See* Figure 11.

[10] and a fastening and centering means for removable locking of the magazine part to a flanged part in a position wherein the membrane portion sealingly abuts against the hole of the flanged part so as to accept the hypodermic needle for introduction into and withdrawal from the container through the membrane portion and the hole.

The fastening device comprises a fastening (186, 187, 188 in Figure 11) and centering (185 in Figure 11) means for removable locking of the magazine part 135 to a flanged part 180 in a position wherein the membrane portion 166 sealingly abuts against the hole 182 of the flanged part 180 so as to accept the hypodermic needle 170 for introduction into and withdrawal from the container 197 through the membrane portion 166 and the hole 182. (Figures 4, 5, and 8). In addition, AllPure's Test Report Summary states:

The TAKEONE® aseptic sampling system transfers fluid when one of the 2mm cannula is actuated, piercing the platinum-cured silicone septum. The fluid being sampled is communicated through the hole at the tip of the cannula for the length of the fully-contained sampling pathway (from needle, through tubing, to collection vessel).

B. AllPure Infringes At Least Dependent Claims 2, 3, 5, 6, and 7 of the '543 Patent

The defendant's TAKEONE Sampler also infringes at least the following claims:

Claim 2 The device as claimed in claim 1, wherein the fastening device comprises a stub axle attached to an upper face of the flanged part and which projects perpendicularly therefrom, said magazine part including a channel therein through which the stub axle extends when in a locked position with the magazine part, said locking part attached to the stub axle so as to interconnect the magazine part and the flanged part.

The fastening device of device 100 comprises a stub axle 186, 187 attached to an upper face 181 of the flanged part 180 and projects perpendicularly from the flanged part 180. The magazine part 135 of device 100 includes a channel therein through which the stub axle 186, 187 extends when in a locked position with the magazine part 135. Locking part 188 is attached to the stub axle so as to interconnect the magazine part 135 and the flanged part 180. *See* Figures 10 and 11.

Claim 3 The device as claimed in claim 2, wherein the membrane portion is formed with a bottom collar that is clamped between the flanged part and the magazine part when in a locked position.

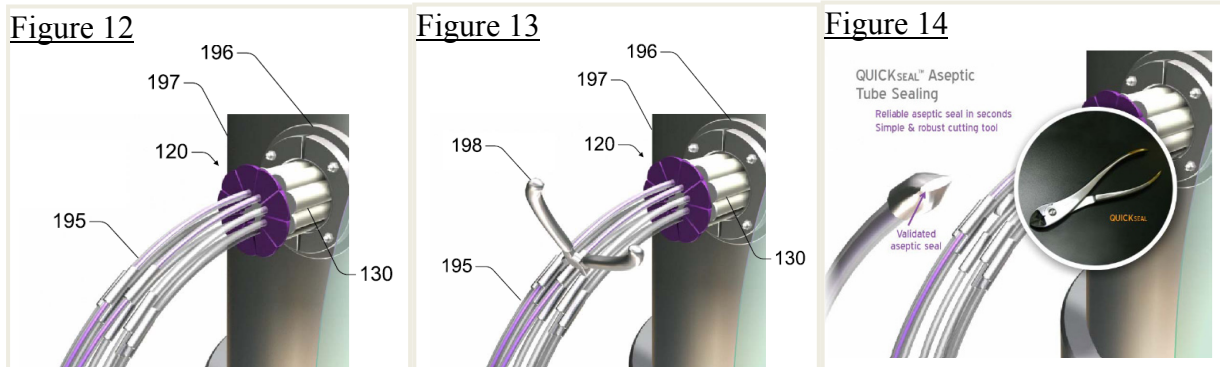
The membrane portion 166 of device 100 is formed with a collar that is clamped between the flanged part 180 and the magazine part 135 when in a locked position, and therefore infringes Claim 3 literally. *See* Figures 4, 10, 11. To the extent that the collar of membrane portion 166 is not literally a “bottom collar” as that term is used in Claim 3, it meets this limitation under the doctrine of equivalents. The collar of the membrane portion 166 performs the same function as the “bottom collar” of Claim 3, which is to improve the sealing effect between the membrane portion 166 and the flanged portion 180. The collar of the membrane portion 166 performs these functions in the same way, which is by being pressed against the seat of the flanged portion, to achieve the same result, which is to increase the self-sealing capacity of the membrane portion 166. (See ’543 Patent at col. 5, ll. 62-68.) Therefore, if it is not literally a “bottom collar,” the collar of the membrane portion 166 is equivalent thereto.

Claim 5 The device as claimed in claim 1, wherein the hypodermic needle is sealingly connected to a collection receptacle, said collection receptacle being expandable upon withdrawal of medium from the container and compressible upon introduction of medium into the container.

The hypodermic needle 170 of device 100 is sealingly connected to a collection receptacle 190, the collection receptacle being expandable upon withdrawal of medium from the container and compressible upon introduction of medium into the container. (Figures 1 and 3.)

Claim 6 The device as claimed in claim 5, wherein the collection receptacle is connected to the hypodermic needle via a hose, and in that a cutting device is provided to sealingly cut said hose in order to free the collection receptacle from the hypodermic needle.

The collection receptacle 190 is connected to the hypodermic needle via a hose 195. (Figures 1, above, and 12-14, below.) Figures 13 and 14 show AllPure's "Stainless Steel QuickSeal Cutter" (Part No. "QS Cutter") 198, a cutting device, sealingly cutting the hose 195 in order to free the collection receptacle from the hypodermic needle.



C. Millipore is unable to determine whether the defendant sells additional devices that may infringe additional dependent claims of the '543 Patent, because the defendant has yet to produce any documents.

The defendant has yet to produce any documents. Consequently, Millipore is unable to determine whether the defendant sells additional devices that may infringe additional dependent claims of the '543 Patent, and summary judgment should be denied on this basis, pending further discovery. *See* Fed. R. Civ. P. 56(d).

II. Because the Defendant's TAKEONE Sampler Infringes the '543 Patent, the Defendant Has Not Proven, and Cannot Prove, Noninfringement

Millipore has established that the defendant's TAKEONE Sampler infringes at least Claims 1, 2, 3, 5, and 6 of the '543 Patent. The defendant asserts that its accused devices do not meet certain limitations of Claim 1. As already shown above, every limitation is met.

A. "Removable, Replaceable Transfer Member"

AllPure asserts, without identifying a single undisputed fact as required by Local Rule 56.1, that its accused device does not have a "removable, replaceable transfer member."

Millipore does not consider it necessary to construe this phrase. To the extent a construction is deemed necessary, the phrase that should be construed is "at least one removable and replaceable transfer member" and it should be construed in accordance with its plain meaning as "one or more transfer members that are capable of being removed from the device and replaced with one or more transfer members."

The defendant seeks to construe "removable, replaceable transfer member" as "A transfer member can be removed from the magazine part and replaced with another transfer member."

1. The accused device has one or more removable, replaceable transfer members

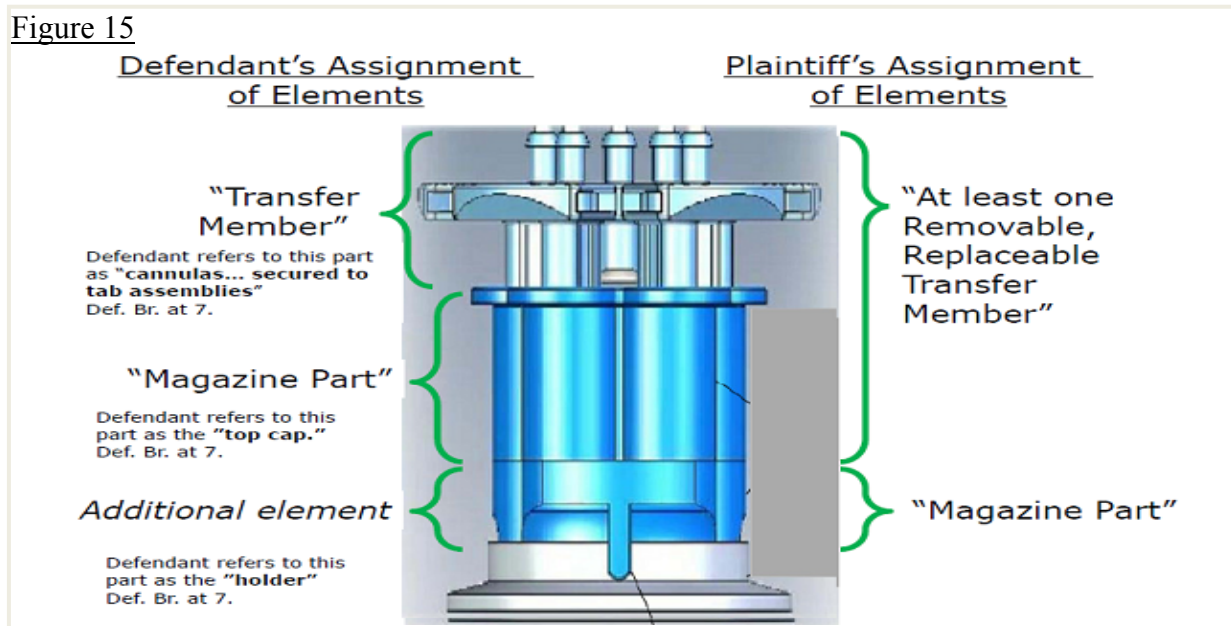
Under either construction, the defendant's TAKEONE Sampler infringes. Under Millipore's construction, the accused device satisfies the limitation, because it clearly has "one or more transfer members that are capable of being removed from the device and replaced with one or more transfer members." *See, e.g.*, Figure 3, above. Under AllPure's proposed construction, it would be reasonable for a fact finder to conclude that in the defendant's TAKEONE Sampler "A transfer member can be removed from the magazine part and replaced with another transfer member." As shown in Figure 3, above, the accused device has a transfer member that can be removed from the magazine part and replaced with another transfer member.

2. The defendant's noninfringement argument is without merit

The defendant's noninfringement argument appears to be based on the legally erroneous assumption that it can affirmatively avoid infringement by demonstrating that it is possible to relabel the pieces of its accused device in such a way that not every limitation is met. The manner in which the defendant appears to be assigning elements to claim limitations is shown in Figure 15 at left. The plaintiff's mapping of elements to limitations, showing infringement, is shown in the same figure, at right.

Based on this apparent mapping, defendant asserts, for example, that "the cannulas of the TAKEONE device [are] not removable and replaceable," Def. Br. at 12, and concludes that "[a]ccordingly, the element of the '543 claims reciting a 'removable, replaceable transfer member' is not present in the TAKEONE device." Def. Br. at 13. However, it is irrelevant

Figure 15



whether AllPure can label its devices in such a way that not all the limitations are met. What is relevant is that Millipore has demonstrated that every limitation of the asserted claims is found in the accused device. *See, e.g., Smithkline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988) ("proof [of infringement] must show that every limitation of the patent

claims asserted to be infringed is found in the accused device, either literally or by an equivalent.”) It is no defense to infringement that the defendant may be able to show that the accused device has some other combination of elements that do not satisfy every limitation of the claims. *See, e.g., A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 703 (Fed. Cir. 1983) (“It is fundamental that one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device.”); *see also Canon Computer Sys. v. Nu-Kote Int’l*, 134 F.3d 1085, 1089-90 (Fed. Cir. 1998) (rejecting defendant’s noninfringement argument, which was premised on alternative labeling and the presence of an additional element).

3. The defendant misreads the prosecution history

The defendant erroneously asserts that Millipore is barred from asserting infringement under the doctrine of equivalents based on prosecution history estoppel. The defendant misreads the prosecution history. The limitation of at least one removable, replaceable transfer member was present in the claims as originally filed: “At least one transfer member. . . whereas the transfer member is removable for replacement thereof after use.” *See* Exhibit D to Harris Decl. (D.I. 32-5).

4. The defendant misstates the doctrine of equivalents.

The defendant misstate the doctrine of equivalents. The defendant asserts that Millipore needs to demonstrate an “*identical*” function in substantially the same way, with substantially the same result.” Def. Br. at 14 (citing *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1333 (Fed. Cir. 2006) (emphasis added)). The standard articulated by the defendant is only the standard for means plus function claims. Because removable, replaceable transfer member is not a means-plus-function limitation, there is no requirement here that that the function of the equivalent be “identical,” but merely “similar.”

5. A reasonable jury could find that the defendant's transfer members are equivalent to the claimed "removable, replaceable transfer members."

Even if the Court adopts the defendant's construction and further holds that under that construction, no reasonable jury could find the accused device to have one or more "removable, replaceable transfer members," a reasonable jury could, at a minimum, find that the defendant's removable, replaceable transfer members are equivalent to the claimed one or more "removable, replaceable transfer members."

The transfer members of the accused device perform the same function, in the same way, with the same result, as the claimed removable, replaceable transfer members. The function of the removable, replaceable transfer members is to be removed from the device and replaced. The transfer members of the accused device perform a similar function. The way this removal and replacement is achieved is by removable securement to the magazine part. The transfer members of the accused device operate in a similar way. The result of having removable, replaceable transfer members is that the transfer members can be removed and exchanged for new transfer members. The accused device achieves the result describe in the specification of the '543 Patent, transfer members are removed from the magazine part and replaced. *See* '543 Patent at col. 6:21-23. ("Alternatively, it is possible to replace used transfer members 1 in one and the same magazine part.")

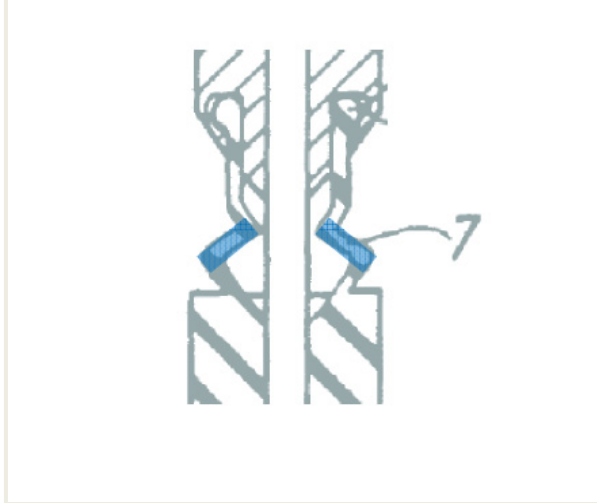
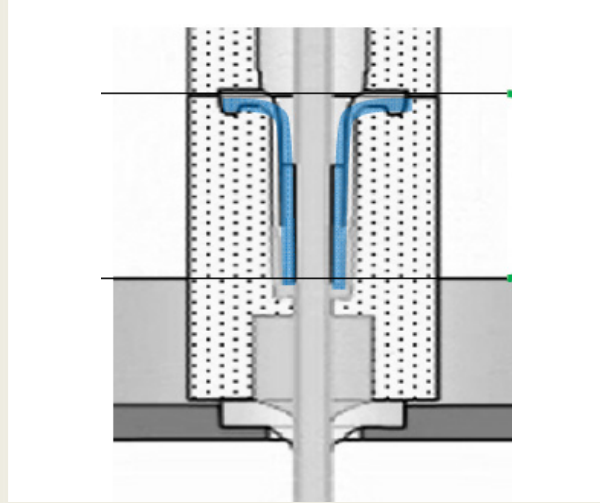
B. "Seal With a First End Having a Bellows-Shaped Part"

AllPure asserts, without citing a single undisputed fact as required by Local Rule 56.1, that the accused device does not have a seal with a first end having a bellows-shaped part.

Millipore seeks to construe "bellows-shaped part" as "a part in which longitudinal deformation is substantially enabled by at least one plate-like structure." *See* Millipore's Opening Brief at 7 to 8. Millipore seeks the same construction for "said bellows part" and "said bellows-shaped part."

Under Millipore's construction, the defendant's TAKEONE Sampler infringes because, as shown in Figure 17, it has a part in which longitudinal deformation is substantially enabled by at least one plate-like structure.

The defendant seeks to construe "bellows-shaped part ... deformable in a longitudinal direction" as "a part that has an accordion like shape when compressed." *See* Defendant's Brief at 15. The defendant's construction should be rejected because it improperly seeks to read limitations from a preferred embodiment into the claims: (a) "accordion like" and (b) "when compressed." The defendant asserts that the concept of an "accordion" is from Figure 4 of the '543 Patent and that "when compressed" is from the specification, which says, "The bellows shaped part 7 ... may be compressed in the lengthwise direction of the needle 5 between the positions illustrated in FIGS. 3 and 4, respectively." '543 Patent, Col. 3, ll. 27-31. In addition to seeking, impermissibly, to import a limitation from the specification into the claims, the defendant is incorrect in its assertion that the bellows-shaped part in Figure 4 is "accordion like." As Dr. Slocum states in his Affidavit at ¶¶ 19 and 20, an accordion is a type of bellows in which the plates have a regular repeating structure to form many convolutions. In Figure 4 of the '543 Patent, the bellows-shaped part has about one and a half convolutions and it does not have a repeating structure to form many convolutions. (See Figure 16, showing at least one plate-like member in blue). "While Figures 3 and 4 of the '543 Patent show a bellows-shaped part, neither figure shows an accordion bellows." Suppl. Slocum Afft. ¶20. The defendant is also incorrect in seeking to import "when compressed" into the construction of "bellows-shaped part ... deformable in a longitudinal direction." The word "deformable," chosen by the patentee in drafting Claim 1 of the '543 Patent, is not so limited as "compressed." Rather, bellows can be compressed, extended, or both.

Figure 16: Bellows in '543 Patent, Fig. 4Figure 17: AllPure's Bellows

A requirement that the bellows-shaped part be “accordion-like” would read the preferred embodiment out of the claims. To the extent, however, that “bellows-shaped part” is construed as an accordion, the AllPure device (see Figure 17, above, showing plate-like member in blue) is as much an accordion as is the structure shown in Figure 4 of the '543 Patent (Figure 16, above). Therefore, AllPure's device infringes with the defendant's construction as well.

C. “Self sealing membrane interiorly formed at an end of said bellows-shaped part”

AllPure asserts, without citing a single undisputed fact as required by Local Rule 56.1, that the accused device does not have a seal with a second end having a self-sealing membrane interiorly formed at an end of said bellow-shaped part.

Millipore's position is that “interiorly formed” does not need to be construed. The term “interiorly formed” would be understood by the trier of fact. To the extent a construction is deemed necessary, the term that should be construed in accordance with its plain meaning as “contained inside of a structure.” It is Dr. Slocum's opinion that one of ordinary skill in the art at the time the invention in the '543 Patent was made would understand “interiorly formed” in Claim 1 of the '543 Patent to mean “contained inside a structure.” Suppl. Slocum Afft. ¶22.

Under Millipore's construction, the defendant's TAKEONE Sampler infringes. In the accused device, the seal has a second end comprising a self-sealing member portion interiorly formed at an end of said bellows-shaped part. "The silicone septa reseal preventing migration of external organisms" *See* AllPure's Test Report Summary.

The defendant seeks to construe "interiorly formed" as "the membrane portion of the seal is integral to the bellows-shaped part of the seal to form a single piece."

The ordinary and customary meaning of a phrase controls, where, as here, the patentee has neither acted as his own lexicographer nor disavowed claim scope in the specification or during prosecution. *See Thorner* 2012 U.S. App. LEXIS 1864 at *4. The ordinary and customary meaning of "interiorly formed" is "contained inside of a structure."

The defendant's proposed construction is improper because it ignores the ordinary and customary meaning and reads a limitation of a preferred embodiment into the claims. The defendant would require that the membrane portion not only be "interiorly formed" at an end of the bellows part, as required by the plain language of the claims, but also that the interiorly formed membrane portion be integral to the bellows part. There is no such limitation. The defendant bases its argument on Figure 3, which is a specific preferred embodiment, and also on its erroneous assumption that "the seal is a single piece." While a preferred embodiment shows a one piece seal, the claims are not so limited. Nor are the claims limited to seals wherein one of the seal parts, the "membrane portion," is integral to the bellows-shaped part. The defendant's proposed construction should be rejected because it impermissibly seeks to read limitations into the term "interiorly formed," under the guise of construing the term "interiorly formed."

As shown in Figures 4 and 5, above, the defendant's TAKEONE Sampler has a seal 160 (Figure 4) having a second end comprising a self-sealing membrane portion 166 (Figures 4 and 5) that is interiorly formed at an end of said bellows part 165 (Figures 4 and 5).

V. Conclusion

The defendant's motion for summary judgment should be denied, and consideration should be given to entry of summary judgment *sua sponte* in favor of Millipore based on the Court's claim construction.

EMD MILLIPORE CORPORATION,
MILLIPORE AB, and
MILLIPORE SAS

By their attorneys,

/s/ Lawrence P. Cogswell III, Ph.D.
Susan G. L. Glovsky BBO# 195880
Lawrence P. Cogswell III, Ph.D. (BBO #664396)
Hamilton, Brook, Smith & Reynolds, P.C.
530 Virginia Road
P.O. Box 9133
Concord, Massachusetts 01742
Telephone: 978-341-0036
Fax: 978-341-0136
susan.glovsky@hbsr.com
lawrence.cogswell@hbsr.com

Dated: February 14, 2012

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on February 14, 2012.

/s/ Lawrence P. Cogswell III, Ph.D.
Lawrence P. Cogswell III, Ph.D

1180074